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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,302	03/12/2004	Jeffrey S. Kiel	455-030	8227

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,302	KIEL ET AL.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 07/30/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment

1. Applicant's arguments, see page 1, filed February 05,2007, with respect to claims 1-16 have been fully considered and are persuasive. The 102 rejection of Chopdekar et al. (US 5,663,415) has been withdrawn. The 102 rejection of Gordziel is maintained and made Final.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordziel (US 6,037,358), for the reasons set forth in the Office Action mailed on November 01, 2006.

The patent '358 discloses a pharmaceutical preparations containing phenylephrine and chlorpheniramine in the form of tannate complex having antitussive, sympathomimetic decongestant and antihistamininc properties superior to the use of either one of the tannate compounds alone (see column 2, lines 12-17). The patent '358 also discloses the preparation of composition for oral administration in the form of powders, capsules, elixirs, syrups, suspensions and preferred forms of tablets containing the unique tannate salt combination in a

conventional manner by the addition of suitable pharmaceutical carriers including fillers, diluents, lubricants and the like as well as conventional and well known binding and disintegrating agents (see column 2, lines 18-65 and column 3, example 2). Additionally for a typically process for the preparations of Pyrilamine tannate and phenylephrine tannate compositions (see US 3,197,370, US 5,599,846 and US 6,287,597). The teaching of the patent '358 possesses all the steps required as recited in claims. Thus, all the claims are anticipated.

4. Applicant's arguments filed on February 05, 2007 have been fully considered but they are not persuasive.

Applicant asserts that the Gordziel reference do not teach all the limitations of independent claims 1 and 5 which requires (i) a separate step of preparing a dispersion, in a pharmaceutically acceptable liquid in the presence of a dispersing agent and (ii) combining the tannate salt complex of the active ingredient without isolation or purification with pharmaceutical excipients to generate a therapeutic dosage form.

The examiner disagrees. Regardless of the characteristic of the claimed dispersing agent, magnesium aluminum silicate has been utilized in formulating a composition containing phenylephrine tannate and pyrilamine tannate in the prior art (Gordziel). Therefore, the use of dispersing agent in making the claimed pheylephrine tannate and pyrilamine tannate containing composition would have been apparent and such dispersing agent is within the broad scope of dispersants defined by function and/or intended use only in the claims.

And also as a dispersant, it is possible to use any polar solvent, without any limitation if it has an appropriate boiling point not exceeding the temperature employed for heating after application, and efficiently disperse the fine particles to form dispersion. Water is a highly polar solvent and also serves as dispersant as evidenced by numerous documents (see EP 779,343 A2, see page 3, lines 30-35). Gordziel in the process of preparing chlorpheniramine tannate and phenylephrine tannate employs purified water as liquid to obtain a suspension formulation. Even though Gordziel as not explicitly recited water as a dispersing agent, it is preventing the clumping and aggregation of the tannate salts formed and aid the efficient distribution of particles of active ingredients.

With the respect to the instantly claimed sequence of adding ingredients by creating separate step of mixing a dispersing agent and tannic acid in a suitable liquid, for example water, to generate the dispersion before adding it to the solution containing phenylephrine tannate and pyrilamine tannate, the examiner maintains that such selection of any order of mixing ingredients is prima facie obvious in the absence of new or unexpected results showing such step is critical.

With respect to the instantly claimed steps of combining the tannate salt complex of the active ingredient without isolation or purification with pharmaceutical excipients to generate a therapeutic dosage form, the patentability of the product is not dependent upon the manner in which is produced unless the process changes the product. In this situation, the prior art teaches the preparation of oral administration in the form of powders, capsules

elixirs, syrups and the preferred tablets or suspensions formulation. Both products in the prior art and the instant invention are drawn to the same composition.

When the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. See In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed.Cir.1983) and In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected on the ground of nonstatutory double patenting over claims 1,3-6, 31-35 and 39 of copending application No 10/047,578. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

The copending application is directed to a composition comprising antihistamine, solvent and dispersing agent, the composition formed from a method comprising steps of (i) forming a solution by dissolving the salt or base of active ingredient in a solvent (ii) forming a dispersion by mixing a dispersing agent and tannic acid (iii) combining the solution and the dispersion, to form tannate salts of the active ingredient and (iv) combining the tannate salts without isolation or purification with suspending agent to produce said composition. The claims of the instant application are drawn to a manufacturing process for the conversion and incorporation of a salt or free base of an active ingredient into a therapeutic liquid or semi-solid dosage form, the process comprising steps of (i) dissolving the salt or free base of the active ingredient in a pharmaceutically acceptable liquid (ii)

forming a dispersion by mixing with a dispersing agent and the tannic acid (iii) combining the tannate salt complex of the active ingredient without isolation or purification with acceptable excipients to generate a therapeutic dosage form. Both require antihistamine active ingredient, solvent and dispersing agent to generate a therapeutic dosage form. Thus the instant claims are directly within the scope of the claims of the copending application and are properly included in the rejection because they are patentably distinct from each other.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

1. No claims are allowed at this time.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr

VICKIE KIM
PRIMARY EXAMINER